

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JOHN P. WHITE  
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NEW YORK, NEW YORK 10036

## PCT

### WRITTEN OPINION

(PCT Rule 66)

SEP - 6 2001

Date of Mailing  
(day/month/year)

31 AUG 2001

Applicant's or agent's file reference

59131-A-PCT

REPLY DUE

within ONE months  
from the above date of mailing

International application No.

PCT/US00/15621

International filing date (day/month/year)

07 JUNE 2000

Priority date (day/month/year)

07 JUNE 1999

International Patent Classification (IPC) or both national classification and IPC  
Please See Supplemental Sheet.

Applicant

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 07 OCTOBER 2001

Name and mailing address of the IPEA/US

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Washington, D.C. 20231

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**I. Basis of the opinion**

1. With regard to the elements of the international application: \*

☒ the international application as originally filed

☒ the description:

pages 1-86 , as originally filed  
 pages NONE , filed with the demand  
 pages NONE , filed with the letter of \_\_\_\_\_

☒ the claims:

pages 87-104 , as originally filed  
 pages NONE , as amended (together with any statement) under Article 19  
 pages NONE , filed with the demand  
 pages NONE , filed with the letter of \_\_\_\_\_

☒ the drawings:

pages 1-29 , as originally filed  
 pages NONE , filed with the demand  
 pages NONE , filed with the letter of \_\_\_\_\_

☒ the sequence listing part of the description:

pages NONE , as originally filed  
 pages NONE , filed with the demand  
 pages NONE , filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
 These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE  
☒ the claims, Nos. NONE  
☒ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

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III. N n-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 5-7, 12, 15, 26-28, 32, 33, 35-37, 39-48, 50-137

because:

- ☐ the said international application, or the said claim Nos. \_ relate to the following subject matter which does not require international preliminary examination (*specify*).

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-7, 35-37 and 39 are so

Claims 5-7, 35-37 and 39 are dependent claims not drafted in accordance with the second and third sentences of Rule 6.4(a). These claims were inadvertently included in the Lack of Unity made in Chapter I.

- ☒ the claims, or said claims Nos. (See Attached) are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. (See Attached).

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☒ the computer readable form has not been furnished or does not comply with the standard.

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**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. statement**

Novelty (N)	Claims	<u>(Please See supplemental sheet)</u>	YES
	Claims	<u>(Please See supplemental sheet)</u>	NO
Inventive Step (IS)	Claims	<u>(Please See supplemental sheet)</u>	YES
	Claims	<u>(Please See supplemental sheet)</u>	NO
Industrial Applicability (IA)	Claims	<u>(Please See supplemental sheet)</u>	YES
	Claims	<u>(Please See supplemental sheet)</u>	NO

**2. citations and explanations**

Claims 1-5, 8-11, 13, 14, 16-25, 29-31, 34, 35, 38, and 49 lack novelty under PCT Article 33(2) as being anticipated by Iwane et al.

Iwane et al. teach an isolated nucleic acid molecule encoding a polypeptide capable of binding with a p75NTR receptor (the recombinant human nerve growth factor), a vector comprising the nucleic acid molecule, a host cell comprising the vector, and method of making and isolating the polypeptide from a host cell culture, and the purified polypeptide. The nucleic acid molecule will necessarily bind to the nucleic acid molecule of Iwane et al.

Claims 1-5, 8-11, 13, 14, 16-25, 29-31, 34, 35, 38, and 49 lack novelty under PCT Article 33(2) as being anticipated by Khursigara et al.

Khursigara et al. teach an isolated nucleic acid molecule encoding a polypeptide capable of binding with a p75NTR receptor (TRAF6), a vector comprising the nucleic acid molecule, a host cell comprising the vector, and method of making and isolating the polypeptide from a host cell culture, and the purified polypeptide. The nucleic acid molecule will necessarily bind to the nucleic acid molecule of Iwane et al.

Claims 1-5, 8-11, 13, 14, 16-25, 29-31, 34, 35, 38, and 49 meet the criteria set out in PCT Article 33(4), because the nucleic acid sequence, vector encoding the sequence, host cell containing the vector, and the purified polypeptide made by the host cell are useful in studying ligand-p75NTR receptor interactions.

----- NEW CITATIONS -----  
NONE

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**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: the description contains nucleic acid and amino acid sequences which are not identified by a SEQ ID NO.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to contain an adequate written description of isolated nucleic acid sequences and amino acid sequences encoding polypeptides capable of binding with a p75NTR receptor. The description is inadequate because: the description does not provide sufficient information with respect to all of the possible nucleic acid sequences and amino acid sequences embraced by the claims.

Claims 1-5, 8-11, 13, 14, 16-25, 29-31, 34, 35, 38, and 49 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not adequately described in writing, as required under PCT Rule 5.1(a)(iii), for the reasons set forth in the immediately preceding paragraph.

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to adequately enable practice of the claimed invention because: the description does not provide sufficient guidance to make all of the nucleic acid sequences and amino acid sequences embraced by the claims.

Claims 1-5, 8-11, 13, 14, 16-25, 29-31, 34, 35, 38, and 49 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not enabled as required under PCT Rule 5.1(a) for the reasons set forth in the immediately preceding paragraph.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

**CLASSIFICATION:**

The International Patent Classification (IPC) and/or the National classification are as listed below:  
 IPC(7): A61K 38/00; C07H 21/02, 21/04; C07K 14/00; C12N 5/00, 5/06, 5/10, 15/00, 15/09, 15/11, 15/12, 15/63 and US  
 Cl.: 435/69.1, 70.1, 320.1, 325, 455; 514/2; 530/350; 536/23.1, 23.5, 24.1

**III. NON-ESTABLISHMENT OF OPINION:**

Claim numbers 12, 15, 32, 33, 36, 37, 53, 54 are so inadequately supported by the description that no meaningful opinion could be formed.

No international search report has been established for claim numbers 26-28, 39-48, 50-52, 55-137.

**V. 1. REASONED STATEMENTS:**

The opinion as to Novelty was positive (YES) with respect to claims NONE.

The opinion as to Novelty was negative (NO) with respect to claims 1-5, 8-11, 13, 14, 16-25, 29-31, 34, 35, 38, 49.

The opinion as to Inventive Step was positive (YES) with respect to claims NONE.

The opinion as to Inventive Step was negative (NO) with respect to claims 1-5, 8-11, 13, 14, 16-25, 29-31, 34, 35, 38, 49.

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-5, 8-11, 13, 14, 16-25, 29-31, 34, 35, 38, 49.

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE.